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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,109	03/26/2004	Jean Francois Bach	IVD 938-2	8031

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EXAMINER	
HISSONG, BRUCE D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,109	BACH ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6-15 and 17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,6-15 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A. Formal Matters

1. The contents of the instant application, including the specification and preliminary amendment, were received 3/26/2004, and have been entered into the record.

2. The oath and declaration, and the request for corrected filing receipt, received on 6/22/2004, have been entered into the record.

3. Claims 2-4, 6-15, and 17-19 are pending and are the subject of this Office Action.

B. Information Disclosure Statement

The information disclosure statement received on 3/26/2004 has been fully considered by the Examiner.

C. Specification

The specification is objected to because the bibliographic data recited in the first line of the specification is not consistent with the bibliographic data sheet. Specifically, application no. 09/125,168 is now US 6,713,053. Appropriate correction is required.

D. Claim Objections

1. The Examiner suggests the syntax of claims 7 and 11 can be improved by amending the claims to read "autologous or syngeneic T lymphocytes from the patient"

2. The Examiner suggests claim 14 be amended to read "wherein said autoimmune disease is insulin-dependent diabetes mellitus."

3. The Examiner suggests that claim 4 be amended to read "autoimmune-type 2 hepatitis", and "autoimmune-type pathogenic mechanisms".

4. Claims 2-4 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 17. When two or more claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, it is not clear how the methods of treatment of claims 2-4 would differ from the method of treatment of claim 17.

5. Claims 7-9 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10. When two or more claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, it is not clear how the pharmaceutical compositions of claims 7-9 would differ from the pharmaceutical composition of claim 11.

6. Claims 12-13 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, it is not clear how a process for producing the pharmaceutical composition of claims 12-13 would differ from the process of claim 14.

E. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2-4, 6-15, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating insulin-dependent diabetes mellitus (IDDM), pharmaceutical compositions, or a process for producing

pharmaceutical compositions, comprising T cells incubated with interleukin (IL)-7, wherein said T cells are thymocytes, does not reasonably provide enablement for methods for treating any other autoimmune disease, compositions, or processes for producing said compositions, comprising any other type of T cell incubated with IL-7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. Ex Parte Forman, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The breadth of the claims is excessive because the claims read on a method of treatment, or a pharmaceutical composition, or a process for producing said compositions, wherein in said method, composition, or process comprises any type of T lymphocytes that were previously incubated in the presence of IL-7. The specification provides guidance and examples showing that IDDM can be treated by administration of thymocytes previously incubated in IL-7. However, it is well known in the art that there are several types of T lymphocytes, including thymocytes and peripheral cell types such as mature $CD4^+CD8^-$ Th1 and Th2 cells, $CD4^-CD8^+$ cytotoxic cells, and also cell types such as "T regulatory-type" T cells. As is also well-known in the art, these cell types are phenotypically and functionally different, with different responses to stimuli such as cytokine stimulation. Thus, a person of ordinary skill in the art would not be able to predict whether all types of T cells, when previously incubated in the presence of IL-7, could be used to treat a patient with an autoimmune disease, and it would require undue experimentation of the part of the skilled artisan to make such a determination.

In regards to claims 7-14, drawn to pharmaceutical compositions and processes for producing pharmaceutical compositions, it is noted that a person of ordinary skill in the art would obviously know how to prepare a pharmaceutical composition. However, claims 7-10 and 11-14 each recite different limitations regarding the diseases to be treated, and the specification provides no guidance or examples on if or how a pharmaceutical composition for several potential diseases would differ. For example, would a composition for treatment of an autoimmune disease generated by a failure in the production of IL-4 (as recited in claims 8 and

12) be different than a composition for treatment of any possible autoimmune disease (as recited in claims 7 and 11). Therefore, without knowing if the claimed methods of treatment are effective for treatment of all possible autoimmune diseases, a person or ordinary skill in the art would not be able to make and use a pharmaceutical composition for treatment of all the possible diseases encompassed by claims 7-14.

Furthermore, the claims 2-4, 6-9, 11-13, 15, and 17-18 read broadly on a large number of potential autoimmune diseases. The specification only provides guidance and examples showing that IDDM can be treated by the claimed methods, but does not provide guidance or examples showing that any other autoimmune disease that can be treated by administration of either IL-7 or thymocytes previously incubated in the presence of IL-7. Because the etiology of many autoimmune diseases is complex and often not well-understood, a person of ordinary skill in the art would not be able to predict which of the many possible autoimmune diseases would respond favorably to an IL-7 based treatment method.

In summary, due to the excessive breadth of the claims, which read on all types of T cells and treatment of a large number of autoimmune disorders, the lack of guidance of examples in the specification showing that any T cell type other than thymocytes can be used to treat any autoimmune disease other than IDDM, and the unpredictability of the art regarding which T cell types would respond favorably after stimulation with IL-7 and be useful for treatment of autoimmune disease, a person of ordinary skill in the art would not be able to use any T cell type other than thymocytes for treatment of any autoimmune disease other than IDDM, without further, undue experimentation.

F. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2-4, 6-15, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims are drawn to a method of treatment, pharmaceutical composition, or process for producing said composition, with said methods, compositions, and process comprising T lymphocytes that were previously incubated in the presence of IL-7. The

omitted steps are: a step, or steps, that details an intended effect of the IL-7 incubation on the phenotype or function of the T lymphocytes. For example, does the claimed method depend on the T lymphocytes acquiring a particular phenotype or biological function in response to incubation with IL-7? Additionally, the claims lack a conclusion step that would indicate to a person or ordinary skill in the art when the goal of the claimed method has been accomplished.

2. Claims 3, 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a method for treating an autoimmune disease generated by a failure in the production of IL-4 connected with a "quantitative and functional deficiency of a T cell". The intended meaning of the phrase "quantitative and functional deficiency of a T cell" is not clear because the claims have already recited "a failure in the production of IL-4", and it is unclear if the "quantitative and functional deficiency" refers to this T cell defect, or some other "quantitative and functional deficiency." In addition, the intended meaning of the phrase "connected with" is also unclear.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites a method of treating a patient with an autoimmune disease wherein the disease is "autoimmune type pathogenic mechanisms in a therapy associated with treating AIDS." The intended meaning of the term "autoimmune type pathogenic mechanisms" is not clear in the context of a method of treatment, because it is not clear how one can treat a mechanism.

G. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application

filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 2-4, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Grabstein *et al* (US 5,681,557). The claims of the instant application are drawn to a method of treating a patient with an autoimmune disease comprising administering to the patient a therapeutically effective dose of IL-7. Grabstein *et al* teaches a method of treating a mammal comprising administration of IL-7 (see claims 1-3). Although Grabstein *et al* does not specifically teach treatment of an autoimmune disease, the methods of Grabstein *et al* and the instant application are not patentably distinct from each other because the process steps of administering IL-7 are the same regardless of whether the purpose is to stimulate an immune response by macrophages/monocytes, or to treat an autoimmune disease such as IDDM (Ex parte Novitski, 26 USPQ 1391). The process claims of Grabstein *et al* would inherently possess the autoimmune disease-treating properties claimed in the method of the instant application. Furthermore, although the *recited* patient populations of Grabstein *et al* and those of the instant application are not identical, in the absence of a specific end-point for the claimed treatment, the claims of the instant application are not drawn to treatment of any specific autoimmune disease. Instead, the claims of the instant application are drawn to the treatment of a patient with an autoimmune disease, who may also be in need of stimulation of macrophages/monocytes to treat an infectious disease. Thus, in reality the patient populations may overlap, and the method taught by Grabstein *et al* would inherently treat a patient with an autoimmune disease, as claimed in the instant application.

2. Claims 2-4, 15, 17 rejected under 35 U.S.C. 102(b) as being anticipated by Williams *et al* (US 5,032,396). The claims of the instant application are drawn to a method of treating a patient with an autoimmune disease comprising administering to the patient a therapeutically effective dose of IL-7. Williams et al teaches a method for inducing platelet production in a mammal by administration of IL-7 (see claims 1-4). Although Williams *et al* does not specifically teach treatment of an autoimmune disease, the methods of Willaims *et al* and the instant application are not patentably distinct from each other because the process steps of administering IL-7 are the same regardless of whether the purpose is to induce production of

platelets, or to treat an autoimmune disease such as IDDM (Ex parte Novitski, 26 USPQ 1391). The process claims of Williams *et al* would inherently possess the autoimmune disease-treating properties claimed in the method of the instant application. Furthermore, although the *recited* patient populations of Williams *et al* and those of the instant application are not identical, in the absence of a specific end-point for the claimed treatment, the claims of the instant application are not drawn to treatment of any specific autoimmune disease. Instead, the claims of the instant application are drawn to the treatment of a patient with an autoimmune disease, who may also be in need of increasing platelet levels. Thus, in reality the patient populations may overlap, and the method taught by Williams *et al* would inherently treat a patient with an autoimmune disease, as claimed in the instant application.

H. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 2-3, 6-15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombert *et al* (cited in the information disclosure statement received on 3/26/2004), in view of Jicha *et al* (J. Exp. Med., 1991, Vol. 174, p. 1511-1515). The claims of the instant application are drawn to a method of treating a patient with an autoimmune disease comprising administering T lymphocytes that have been incubated in the presence of IL-7. The claims are further drawn to treatment of an autoimmune disease that is generated by the failure of Th2 cells to produce IL-4, and specifically due to a deficiency in IL-4 production by the subset of cells that is either $HSA^-/CD4^-CD8^-/CD44^+/TCR\text{-}\alpha\beta^+/V\beta8^+/NK1.1^+$ or $HSA^-/CD4^+CD8^-/CD44^+/TCR\text{-}\alpha\beta^+/V\beta8^+/NK1.1^+$. Finally, the claims of the instant application specifically recite treatment of IDDM by the claimed method.

Gombert *et al* teaches that Vβ8-restricted $TCR\text{-}\alpha\beta^+/CD44^+$ thymocytes produce IL-4, and that said production of IL-4 by this subset of thymocytes is impaired in Non-obese diabetic (NOD) mice. Gombert *et al* also teach that this defect in IL-4 production by this subset of thymocytes can be overcome by treating the thymocytes with IL-7. Gombert *et al* is silent

regarding a method of treating a patient by administration of T cells that were previously incubated in the presence of IL-7. Jicha *et al* teach a method of adoptive immunotherapy for treatment of cancer comprising administration of syngeneic T cells that had been incubated in presence of IL-7 (see abstract, and p.1511-1522 – materials and methods section).

Therefore, a person of ordinary skill in the art, at the time the instant invention was made, would have been motivated to combine the teachings of Gombert *et al* with those of Jicha *et al* to practice the instant invention as claimed. Gombert *et al* would have provided the motivation to correct the IL-4 deficiency observed in a mouse model of diabetes by treating $HSA^-/CD4^-CD8^-/CD44^+/TCR\text{-}\alpha\beta^+/V\beta8^+/NK1.1^+$ or $HSA^-/CD4^+CD8^-/CD44^+/TCR\text{-}\alpha\beta^+/V\beta8^+/NK1.1^+$ thymocytes with IL-7. Jicha *et al*, by teaching a successful method of adoptive immunotherapy, would have provided the motivation to incubate autologous or syngeneic $HSA^-/CD4^-CD8^-/CD44^+/TCR\text{-}\alpha\beta^+/V\beta8^+/NK1.1^+$ or $HSA^-/CD4^+CD8^-/CD44^+/TCR\text{-}\alpha\beta^+/V\beta8^+/NK1.1^+$ thymocytes in the presence of IL-7 and administer them to an individual with an autoimmune disease characterized by IL-4 deficiency. Furthermore, following the teachings of Gombert *et al* and Jicha *et al* would teach the skilled artisan the appropriate cell types, cytokines, and methods to practice the instant invention, and thus the skilled artisan would also have a reasonable expectation of success.

I. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 2-4, 15, and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,713,053. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of US 6,713,053 recites a method for the treatment of IDDM comprising administering to a patient in need a therapeutically effective amount of IL-7. As stated above in the 35 U.S.C. 102(b) and 103(e) rejections, the claims of the instant application are not drawn to the treatment of a specific autoimmune disease, but rather to treatment of a patient with an autoimmune disease. Because the patient treated by the methods of the instant application could be a patient with IDDM, it would be obvious to use the method disclosed by U.S. Patent No. 6,713,053 to treat that patient. Furthermore, even if the claims of the instant application were drawn to the treatment of a specific autoimmune disease, US 6,713,053, in column 3, lines 7-17, discloses a number of autoimmune disorders treatable by IL-7 administration. Furthermore, column 2, line 65 – column 3, line 6 of US 6,713,053 teaches the autoimmune diseases with the same limitations as claims 2 and 3 of the instant application. Therefore, it would be obvious to a person or ordinary skill in the art to practice the claims of the instant invention by following the disclosure of US 6,713,053.

2. Claims 2-4, 7-15, and 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,713,053 in view of Jicha *et al.* The subject matter of the claims of the instant application has been previously discussed, and the disclosures of US 6,713,053 and Jicha *et al* are discussed above, and in the 35 U.S.C. 103 rejections, respectively. A person of ordinary skill in the art would be motivated to follow the disclosures of US 6,713,053 and Jicha *et al* to practice the invention of the instant application because US 6,713,053 teaches that autoimmune diseases, including IDDM, can be treated by administration of IL-7, while Jicha *et al* teaches a method of adoptive transfer of IL-7 treated T cells. Thus, US 6,713,053 would provide the motivation to use IL-7 in a method of treating a patient with an autoimmune disease, and Jicha *et al* would provide the motivation to effect said treatment by administration of T cells that were cultured in the presence of IL-7. By disclosing specific methods of treatment, US 6,713,053 and Jicha *et al* would also provide a

reasonable expectation of success in practicing the invention of the instant application commensurate in scope with the claims.

J. Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER